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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,738	KAWAMURA ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the Amendments and Remarks filed on 4/3/3008. Claims 1 and 4-9 have been amended and claims 2-3 and 10-38 have been cancelled. Accordingly, claims 1 and 4-9 are pending and examined on the merits herein.

Status of Rejections/Objections

1. In view of the Applicant's remarks and amendments to the title, abstract, and specification, the objections to the specification are herein withdrawn.

2. In view of Applicant's cancellation of claims 2-3, the rejection of claims 2-3 on the ground of nonstatutory obviousness-type double patenting over copending Application No. 10/574696 and under 35 U.S.C. 102(b) as anticipated by Gil et al. (US 4,544,559) are herein withdrawn. The rejections of claim 2 under 35 U.S.C. 102(b) as anticipated by Gazzani (US 5,050,230) and Gazzani (US 5,182,269) are also withdrawn.

3. The rejection of claims 1 and 4-9 on the grounds of nonstatutory obviousness-type double patenting over claims 1 and 3-15 of copending Application No. 10/574696 are maintained for the reasons of record, but has been modified to address Applicants' amendment to claim 1.

4. The Applicants' arguments with respect to the rejection of claims 1 and 6-9 under 35 U.S.C. 102(b) as anticipated by Gil et al. (US 4,544,559) have been fully considered but were not found persuasive. Thus the rejection is maintained for the reasons of record, but has been modified to address Applicant's amendment to claim 1.

5. In view of the Applicant's amendments to claim 1, the rejections of claims 1-2 and 4-9 under 35 U.S.C. 102(b) as anticipated by Gazzani (US 5,050,230) and Gazzani (US 5,182,269) are herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied in the instant application. The newly applied rejections are necessitated by the amendment of claims 1.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15 of copending Application No. 10/574696.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition for applying to the skin containing a purine nucleic acid-related substance selected from adenosine monophosphate or salts thereof, and a pyrimidine nucleic acid-related substance selected from uridine monophosphate and salts thereof, while the copending claims are drawn to the same composition for promoting collagen production. The recitation of "for applying to the skin" in the instant claims and "for promoting collagen production" in the copending claims have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gil et al. (US 4,544,559).

Gil et al. teaches a composition for nucleotide enriched humanized milk containing the nucleotides cytidine monophosphate (CMP), guanosine monophosphate (GMP) and inosine monophosphate (IMP), adenosine monophosphate (AMP), and uridine monophosphate (UMP) (see abstract and column 1, lines 64-68).

Claim 6 further limits the composition of claim 1 to containing the adenosine monophosphate or salt thereof in a ratio of 0.01 to 100 parts by weight per part by weight of uridine monophosphate or salt thereof.

Gil et al. further teaches that the concentration of the nucleotides in a powdered form of the milk are: 1.12 mg/100 g of CMP (0.00112% by weight); 1.32 mg/100 g of AMP (0.00132% by weight); 1.49 mg/100mg GMP (0.00149% by weight); 3.42 mg/100 g of UMP (0.00342% by weight); and 0.45 mg/100 g IMP (0.00045% by weight) (see

abstract, column 11, Table V, and claim 1). AMP is the purine nucleic acid-related substances while CMP is the pyrimidine nucleic acid-related substances. The ratio of UMP to AMP is 0.00342% by weight to 0.00132% by weight or approximately 2.59 parts by weight the pyrimidine nucleic acid-related substance per part by weight of purine nucleic acid-related substance. Therefore, the limitations of the instant claim 6 are met.

Claims 7-9 indicate intended uses for the composition of claim 1, including anti-wrinkle, anti-aging, anti-dandruff, wound healing, and hair growth effects, etc. Note that the intended use of a product carries no patentable weight. Therefore, the limitations of the instant claims 7-9 are also met.

Response to Arguments

8. The Applicant's arguments filed 4/3/2008 averring the instantly claimed invention being differed from Gil et al. in that it is an external composition, and Gil et al. discloses a composition for nucleotide enriched humanized milk, which is taken orally, have been considered, but are not found persuasive. The examiner notes that the recitation "for applying to the skin" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150,

152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, because the composition of Gil et al. meets all the structural limitations of the instant claims, it is presumed to be capable of performing the intended, i.e. applying the skin.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 4-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Ogoshi (US 4,758,553).

The instant claims are directed to compositions for applying to the skin, comprising adenosine monophosphate or salt thereof, and uridine monophosphate or salt thereof.

Ogoshi teaches a composition of nucleic acid components for nutritional replacement (see abstract). Suitable examples of nucleotides include adenosine monophosphate (AMP) and uridine monophosphate (UMP), or pharmaceutically acceptable salts thereof (see column 23, lines 4-29). In a formulation example, Ogoshi teaches a parenteral solution comprising 5'-AMP·2Na (the sodium salt of AMP) in 2.34% (w/v), and 5'-UMP·2Na (the sodium salt of UMP) in 1.65% (w/v) (see column 7, lines 11-39). Thus, the weight ratio of the pyrimidine nucleic acid-related substance (5'-UMP·2Na) to the purine nucleic acid-related substance (5'-AMP·2Na) is 0.705, as claimed in the instant claim 6.

Ogoshi does not teach the compositions for "applying to the skin" as claimed in the preamble of the instant claim 1, or recite the intended uses for the composition as claimed in the instant claims 7-9. Ogoshi does not explicitly teach the concentrations of AMP or UMP in weight percentages.

As stated above, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re*

Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, absent evidence to the contrary, the composition taught by Ogoshi is capable of being applied to the skin, as an anti-aging composition etc., because it meets all the structural limitations as claimed.

In regards to the concentrations of AMP and UMP, the concentrations of these components in weight-volume percentage (w/v%) are presumed to be similar to the concentrations of these components in percent by weight, absence evidence to the contrary. This is because the solutions taught Ogoshi are dilute solutions in water, and will likely have density close to 1 g/mL. The g/100 mL in the w/v% is equivalent to g/100g when the density of the solution is equal to 1 g/mL, and w/v% and w/w% become equivalent. Thus, the concentrations of AMP and UMP in w/v% as taught by Ogoshi are expected to fall within the weight percentage ranges as claimed.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JLK

/San-ming Hui/
Primary Examiner, Art Unit 1617